NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK A/S, Plaintiff, v. SANOFI-AVENTIS U.S. LLC, et al., Defendants.	CIVIL ACTION NO. 07-3206 (MLC) **MEMORANDUM OPINION & ORDER**

COOPER, District Judge

Plaintiff, Novo Nordisk A/S ("Novo"), commenced this action against defendants, Sanofi-Aventis U.S. LLC ("Sanofi U.S."), Sanofi-Aventis, and Sanofi-Aventis Deutschland GmbH ("Sanofi Germany" and, with Sanofi U.S., "Sanofi"), alleging, inter alia, that they infringed one or more claims of its United States Patent No. 7,241,278 ("'278 Patent") by importing, selling, or offering to sell their SoloStar product in the United States. (See dkt. entry no. 59, Am. Compl.) Sanofi U.S. and Sanofi Germany separately filed answers to the Amended Complaint, which include counterclaims against Novo seeking, inter alia, a declaration that (1) they are immune from Novo's claims in this action, (2) the '278 Patent has not been infringed, (3) the '278 Patent is invalid, (4) the '278 Patent is unenforceable because Novo improperly used it to interfere with competition and extend its monopoly beyond the scope of the patent, and (5) the '278

Patent is unenforceable because Novo engaged in inequitable conduct. (Dkt. entry no. 87, Sanofi U.S. Countercls., Answer & Affirmative Defenses; dkt. entry no. 106, Sanofi Germany Countercls., Answer & Affirmative Defenses.)

The parties dispute the proper construction of claims 1 and 7-26 of the '278 Patent. The Court has (1) considered the papers submitted by the parties, and (2) heard oral argument on June 11, 2009, and thereby conducted its Markman hearing. See Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). Accordingly, the Court hereby issues the following findings of fact and conclusions of law with respect to its construction of the '278 Patent's claims.

BACKGROUND AND FACTUAL FINDINGS

I. The Parties

Novo is a Denmark corporation with its principal place of business in Denmark. (Dkt. entry no. 8, Novo Prelim. Inj. Br. at 4.) Novo's business focuses primarily on developing products to assist persons with diabetes, which is characterized by persistently high blood sugar levels. (See id. at 4-5.) Novo developed the first insulin injection pen in 1985. (Id. at 6.) Insulin injection pens have a needle where an ink pen would have its tip and a push button at the opposite end. (Id.) With an insulin injection pen, the user does not have to draw insulin from a separate vial, but instead rotates a knob on the pen to

set the correct dosage amount. (Id.) Novo has developed more advanced insulin injection pens, including pens that are disposable, have a 3-milliliter insulin cartridge, are designed for persons with poor eyesight or reduced dexterity, and have a built-in blood glucose monitor. (Id. at 8.) More recently, Novo developed the FlexPen, a commercial embodiment of the '278 Patent, which was issued to Novo on July 10, 2007. (See id. at 2; dkt. entry no. 233, Aff. of David R. Dehoney, Ex. A, '278 Patent.) The '278 Patent claims an insulin injection pen that, inter alia, requires less force to inject the insulin medication and prevents the user from dialing up a dose in excess of the amount of insulin remaining in the pen. (See Novo Prelim. Inj. Br. at 9-11.)

Sanofi U.S. is a Delaware limited liability company with its principal place of business in New Jersey, and Sanofi Germany is a German corporation with its principal place of business in Germany. (Sanofi U.S. Countercls., Answer & Affirmative Defenses at 41; Sanofi Germany Countercls., Answer & Affirmative Defenses at 42.) In 2007, Sanofi introduced SoloStar, a disposable insulin delivery device, in the United States. (Dkt. entry no. 152, Sanofi Prelim. Inj. Br. at 2.) Novo alleges that SoloStar infringes claims 1 and 7-26 of its '278 Patent. (Dkt. entry no. 236, Novo Br. at 1.)

II. The '278 Patent

The '278 Patent discloses "[a]n injection device for injection of set doses of medicine from a cartridge, in which syringe a dose is set by screwing a nut up along a threaded piston rod, whereby a dose setting drum . . ., and an injection button, which is elevated over the end of the syringe, are moved axially a distance which is larger than the axial movement of the nut." ('278 Patent at Abstract.) It is composed of 28 claims, but only claims 1, 8, 12, 16, 22, and 25 are independent. (See id. at cols. 7-10.) Claims 1 and 7-26 are the claims at issue here. Claim 1 is representative of the claims at issue and describes:

> 1. A drug delivery device comprising:
> a piston rod having at least one threaded portion;
> a dose dial sleeve threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale;
> a drive sleeve for driving the piston rod; and
> a clutch, which is comprised of one or more components that releasably couples the dose dial sleeve and the drive sleeve; and wherein:
> (i) during the dose setting operation the dose dial sleeve and the drive sleeve are coupled by the clutch so that they rotate together; and
> (ii) during injecting of medication from the device, the dose dial sleeve is decoupled from the drive sleeve and so that it rotates back to an original pre-dose setting position upon completion of the injection but the drive sleeve does not rotate during injecting of medication but instead moves in a longitudinal direction toward an injecting end of the device.

(Id. at col. 7, lines 18-40 (numerical references to portions of diagrams omitted).)

Novo asserts that claims 7, 15-21, and 25-26 also describe a clutch mechanism, and, in addition, describe a mechanical advantage created by requiring the drive sleeve to move a greater distance than the piston rod during injection. (Novo Prelim. Inj. Br. at 24.) Claim 25, for example, states:

> A drug delivery device comprising:
> a piston rod;
> a dose dial threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale; a drive sleeve for transmitting a force that is received at one end of the device to drive the piston rod; and
> wherein the dose dial and the drive sleeve are releasably coupled so that when the device is in a dose setting mode, the dose dial and drive sleeve rotate together and allow a predetermined dose to be set, and during the injection of the predetermined dose the dose dial and the drive sleeve are decoupled and the dose dial rotates with respect to the drive sleeve and rotates to a zero position upon completion of the injection and the drive sleeve moves axially toward an injecting end of the device and wherein the drive sleeve moves a distance that is greater than a distance that is moved by the piston rod during the injecting of the predetermined dose.

('278 Patent at col. 10, lines 20-41.) Novo also asserts that claims 14 and 18 describe both a clutch mechanism and a "dose limiter" or "end-of-content" function, which prevent the user from dialing up a dose exceeding the amount remaining in the pen. (Novo Prelim. Inj. Br. at 24; see '278 Patent at col. 8, lines

65-67 (noting that device comprises "a dose limiter that prevents a dose from being set that is larger than the contents remaining in the device"); id. at col. 9, lines 31-35 (noting that device comprises "a dose setting limiter that prevents a dose that is larger than that remaining in the device from being set").)

DISCUSSION AND CONCLUSIONS OF LAW

I. Applicable Legal Standards

An infringement inquiry is a two-step process. First, the Court must determine the scope and meaning of the patent claims as a matter of law. Markman, 52 F.3d at 979. Second, the allegedly infringing device is compared to each claim at issue to determine if "all of the limitations of at least one claim are present, either literally or by a substantial equivalent, in the accused device." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1323 (Fed. Cir. 2002).

There is a "'heavy presumption' that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). The ordinary and customary meaning of a claim term is the meaning a "person of ordinary skill in the art in question" would give to such term on the effective filing date of the patent application. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). Such a person is deemed to interpret the claim term in the

context of the entire patent, including the specification and prosecution history. Id.

The specification is "always highly relevant to the claim construction analysis" and is "the single best guide to the meaning of a disputed term." Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318 (Fed. Cir. 2006) (internal quotation omitted). The specification may contain an intentional disclaimer or a disavowal of claim scope by the inventor, in which case the inventor's intention, expressed in the specification, is dispositive. Phillips, 415 F.3d at 1316. It is, however, improper to read a limitation from the specification into the claims. Teleflex, Inc., 299 F.3d at 1326.

The Court also considers the patent's prosecution history. Phillips, 415 F.3d at 1317. The prosecution history provides evidence of how the inventor understood the patent. Id. The prosecution history also demonstrates whether the inventor limited the invention during the course of the patent prosecution, thus narrowing the scope of the ultimately patented product. Id. Because the prosecution history reflects the ongoing negotiations between the inventor and the United States Patent and Trademark Office, it is often less clear and less useful than the specification. Id.

A claim term should generally be given its ordinary meaning unless the patentee "clearly set forth a definition of the

disputed claim term in either the specification or prosecution history." CCS Fitness, Inc., 288 F.3d at 1366. A claim can only be assigned a narrower scope "if there is some indication in the patent or the prosecution history that the term . . . was meant to have a more restrictive meaning as used in the patent, or a broader meaning was disclaimed during prosecution." Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1331 (Fed. Cir. 2007). Thus, claim terms "take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, Inc., 299 F.3d at 1327.

II. Legal Standards Applied Here

At this point in the claim construction process, the parties' dispute centers on whether the claims at issue should be construed to require a "gearbox" and a "non-rotatable piston rod." (See Novo Br. at 17-29; dkt. entry no. 252, Sanofi Br. at 11-39.) The plain language of claim 1, which is representative of the claims at issue, does not explicitly recite, or even reference, a gearbox or a non-rotatable piston rod. (See '278 Patent at col. 7, lines 18-40.) Claim 1 is broadly written and does not contain gearbox and non-rotatable piston rod

limitations. (See id.) Thus, the ordinary and customary meaning of the terms in claim 1 does not include a gearbox or a non-rotatable piston rod. See Phillips, 415 F.3d at 1312 (emphasizing that patent's claims define the invention). Claim 1 will therefore be construed to require a gearbox and a non-rotatable piston rod only if "the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." See Teleflex, Inc., 299 F.3d at 1327.

Sanofi argues that the specification shows that claim 1, and all asserted claims, should be construed to require a gearbox because a gearbox is essential to the invention. (Sanofi Br. at 14-15.) Sanofi asserts that the specification characterizes the invention as requiring a gearbox and, in support, identifies a statement in the specification providing that "[i]t is an objective of the invention to provide an injection device, which combines the advantages of the devices according to the prior art without adopting their disadvantages and to provide a device wherein is established a direct gearing . . . between the injection button and the piston rod." (Id. at 16; see also '278 Patent at col. 2, lines 42-49.) Sanofi also points to language in the specification providing that "which injection device is

according to the invention characterised in that a gearbox is provided" for further support of its argument. (Sanofi Br. at 17; see also '278 Patent at col. 2, lines 60-62.) According to Sanofi, this language in the specification shows that the invention's singular objective involves use of direct gearing. (Sanofi Br. at 16-17.) Sanofi also contends that the specification's repeated emphasis on a gearbox further illustrates that the invention requires a gearbox. (Id. at 18-20.)

Sanofi also argues that the specification demonstrates that the invention, not just the preferred embodiment, requires a gearbox. (Id. at 23-26.) Sanofi asserts that an injection device with a gearbox is the only device described in the specification capable of meeting the invention's stated objective. (Id. at 23.) Further, Sanofi contends that the specification disclaims threaded devices by describing prior art with threading and stating that with "this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces. Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred." (Id. at 27; '278 Patent at col. 2, lines 4-8.) Sanofi also argues that in statements Novo made during the prosecution of the '278 Patent, Novo expressly defined the invention to require a gearbox. (Sanofi Br. at 30.)

Novo argues that the references to a gearbox in the specification refer to the preferred embodiments, not the invention as a whole. (Novo Br. at 18.) Novo asserts that it did not act as its own lexicographer here and did not define the claim terms in the specification to mean other than their ordinary meaning. (Id. at 22.) Further, Novo argues that nothing in the specification shows that it intended to disavow or disclaim the invention without the gearbox limitation. (Id.) Rather, Novo contends, the specification makes clear that the gearbox limitation applies only to the preferred embodiments. (Id.) Novo further contends that the doctrine of claim differentiation confirms that the disputed claim terms do not include a gearbox requirement. (Id. at 27.) Novo also asserts that the prosecution history, specifically amendments to the '278 Patent cancelling claims reciting a gearbox and replacing them with new claims without a gearbox, shows that Novo intended to claim a device that did not require a gearbox. (Id. at 26.)

The Court concludes that the disputed claims do not require a gearbox or a non-rotatable piston rod. The Court finds that Novo did not, in the specification, act as its own lexicographer. (See '278 Patent.) Nothing in the specification defines the claim terms in a fashion other than their ordinary meaning. (See id.) In contrast, the court in Astrazeneca AB v. Mutual Pharmaceutical Co., relied upon by Sanofi, found that the

"inventors deliberately acted as their own lexicographers" in concluding that the specification limited the scope of the claim terms. (See Sanofi Br. at 18-19, 26-27.) 384 F.3d 1333, 1339 (Fed. Cir. 2004).

The Court also finds that the specification and the prosecution history do not contain a clear disavowal of the claims' broad scope. The specification states that "an objective of the invention [is] to provide . . . a device wherein is established a direct gearing . . . between the injection button and the piston rod." ('278 Patent at col. 2, lines 42-49 (emphasis added).) The language used, specifically "an objective" rather than "the objective," indicates that there are multiple objectives of the invention and that use of a "direct gearing" is not the invention's sole objective. (See id.) Further, it is not necessary for every claim in the patent to be directed to every objective in the specification. See Honeywell Inc. v. Victor Co. of Japan, Ltd., 298 F.3d 1317, 1325-26 (Fed. Cir. 2002). Here, some of the claims not at issue, such as claim 2 and claim 4, do require a gearbox and thereby satisfy the objective of providing direct gearing. (See '278 Patent at col. 7, lines 41-46, 57-62.) The disputed claims, therefore, do not have to address the direct gearing objective; rather, they can address other objectives of the invention, such as providing "an injection device, which combines the advantages of the devices

according to the prior art without adopting their disadvantages." (Id. at col. 2, lines 42-45.) See Honeywell Inc., 298 F.3d at 1325-26.

The specification does not indicate that the invention, as opposed to the preferred embodiment, requires a gearbox. The specification only describes an embodiment that includes a gearbox. (See '278 Patent at col. 2 lines 66-67 - col. 7, lines 1-16.) That the specification discloses only an embodiment with a gearbox, however, does not limit the invention as a whole. See Saunders Group, 492 F.3d at 1332 ("A patent that describes only a single embodiment is not necessarily limited to that embodiment."); Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (emphasizing Federal Circuit's express rejection of notion that where patent describes only one embodiment of invention, then patent claims must be construed as limited to that embodiment). Further, the specification does not restrict the scope of the invention to injection devices having a gearbox, but rather uses open-ended language indicating that the described embodiment is but one form the invention can take. (See '278 Patent at col. 2, lines 50-65 (explaining that the patent's objectives "can be obtained" by an injection device containing, among other things, a gearbox); id. at col. 2, line 66-67 - col. 3, lines 1-18 (describing "a preferred embodiment"); id. at col. 3, lines 35-37 (discussing "another embodiment of an

injection device according to the invention").) See Liebel-Flarsheim Co., 358 F.3d at 908 (refusing to limit scope of claim terms based on specification where all embodiments described in specification included the limitation but the specification did not contain a "clear disavowal of embodiments lacking [the limitation]"). Here, the specification does not contain a clear disavowal of embodiments lacking a gearbox. See Liebel-Flarsheim Co., 358 F.3d at 908.

SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., relied upon by Sanofi, presents a much different situation. (See Sanofi Br. at 21, 26-27.) 242 F.3d 1337 (Fed. Cir. 2001). In SciMed Life Systems, the court concluded that the specification disclaimed the broad scope of the disputed claim language. 242 F.3d at 1342-45. In reaching this conclusion, the court found "most compelling" that the specification stated that a structure, which was described as including the disputed limitation, is "the basic . . . structure for all embodiments of the present invention contemplated and disclosed herein." Id. at 1343-44 (quoting United States Patent Nos. 5,156,594, 5,217,482, and 5,395,334). In light of this "broad and unequivocal" language, the court determined that the disputed limitation could not reasonably be interpreted as limited only to the preferred embodiment. Id. at 1344. In contrast, the specification here does not include broad and unequivocal language explicitly

stating that "all embodiments of the present invention" include a gearbox. (See '278 Patent.) See SciMed Life Sys., 242 F.3d at 1344. Rather, the specification's language is non-restrictive and makes clear that the gearbox limitation applies to preferred embodiments, not to all embodiments, of the invention. (See '278 Patent at col. 2, lines 42-67 - col. 3, 1-18.)[1]

The specification's comments on prior art, specifically prior art utilizing threading, do not amount to a disavowal of threading from the scope of the disputed claims. The specification merely notes a disadvantage of threading as used in prior art, namely that the threading previously used resulted in loss of the transformed force due to friction between the sliding surfaces, and expresses a preference for traditional gearing. (See '278 Patent at col. 2, lines 1-8.) These comments, while expressing the patentee's preference for gearing, do not disclaim threading, especially since the patent's stated objectives do not indicate an intention to avoid use of all threading. (See id. at

[1] Alloc, Inc. v. International Trade Commission is also distinguishable on this basis. In Alloc, Inc., the court, in finding that a limitation from the specification narrows the claims, determined that the specification showed that "the invention as a whole, not merely a preferred embodiment, provides for [the disputed limitation]." 342 F.3d 1361, 1369 (Fed. Cir. 2003). Further, the court concluded that the specification made clear that the disputed limitation must be included in every embodiment of the invention. Id. at 1370. In contrast, this Court finds that the specification here shows that the gearbox limitation applies only to preferred embodiments, not the invention as a whole.

col. 2, lines 42-45 (stating only that an objective is to combine "the advantages of the devices according to the prior art without adopting their disadvantages" without discussing the specific disadvantages to be avoided).) See Ventana Med. Sys., Inc. v. BioGenex Labs., Inc., 473 F.3d 1173, 1180-81 (Fed. Cir. 2006) (rejecting contention that general statements indicating intention to improve upon prior art should be interpreted to disclaim every feature of prior art discussed in specification). Further, the specification does not indicate that use of threading is impossible or unsuitable to the invention. (See '278 Patent.) See Saunders Group, 492 F.3d at 1333 (finding that specification did not support narrow construction of claims where specification, although commenting on disadvantages of prior art, did not state that the only way to overcome disadvantages of prior art is through use of disputed limitation).

This contrasts with the patent's language in Honeywell International, Inc. v. ITT Industries, Inc. in which the specification explained specifically why a material used in the prior art would not be suitable for use in the claimed invention. 452 F.3d at 1320. There, the court found the specification's "repeated derogatory statements" concerning the material used in the prior art to be the equivalent of a disavowal. (Id.) Here, in contrast, the specification merely discloses a disadvantage found in the prior art and expresses a preference for gearing;

there are neither "repeated derogatory statements" about threading, nor statements denigrating threading's applicability to the claimed invention. (See '278 Patent.) Honeywell Int'l, 452 F.3d at 1320. Thus, the Court finds that the specification's comments on the prior art, specifically prior art involving threading, do not amount to a clear disavowal of all threading.

The doctrine of claim differentiation also supports construing the disputed claims as not requiring a gearbox. Under this doctrine, the presence of a dependent claim adding a limitation raises a presumption that the same limitation is not present in the independent claim. Phillips, 415 F.3d at 1315; RF Del., Inc. v. Pac. Keystone Techs., Inc., 326 F.3d 1255, 1263 (Fed. Cir. 2003). Here, claim 2 and claim 4, both of which explicitly include a gearbox limitation, are dependent on independent claim 1. (See '278 Patent at col. 7, lines 41-46, lines 57-62.) Thus, applying the doctrine of claim differentiation, there is a presumption that the gearbox limitation present in dependent claim 2 and claim 4 is not present in independent claim 1. See Liebel-Flarsheim Co., 358 F.3d at 910 (concluding that "juxtaposition of independent claims lacking any reference to a pressure jacket with dependent claims that add a pressure jacket limitation provides strong support for . . . argument that the independent claims were not intended to require the presence of a pressure jacket"); see also Saunders

Group, 492 F.3d at 1331. The doctrine of claim differentiation therefore further supports a broad construction of the disputed claims.

The prosecution history also indicates that the disputed claims should be construed as not requiring a gearbox. In 2007, Novo amended its patent application by canceling claims reciting a gearbox and replacing them with new claims that do not recite a gearbox. (Aff. of David R. Dehoney, Ex. M, Second Preliminary Amendment at STR0096534-544; id., Third Preliminary Amendment at STR0096546-558.) This demonstrates Novo's intention to broaden its claims and to claim a device that does not require a gearbox. See Liebel-Flarsheim Co., 358 F.3d at 909 (finding "no dispute" that claims were intended to include devices without pressure jackets where, during prosecution, applicant sought to omit claim references to pressure jackets so as to encompass competitor's jacketless product). Further, the statement Novo made during prosecution, which Sanofi highlights as evidence that the invention requires a gearbox, was made before Novo filed amendments dropping claims reciting a gearbox requirement and adding claims that do not recite a gearbox. (See Sanofi Br. at 30; dkt. entry no. 264, Novo Reply Br. at 16; see also dkt. entry no. 252, Decl. of Agnes Antonian, Ex. L, Amendment Under 37 C.F.R. 1.111 at STR0096436-442.) Thus, the prosecution history supports a broad construction of the disputed claims.

The Court concludes that the specification and the prosecution history do not include expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope, that demonstrate an intent to limit the invention to devices that have a gearbox and a non-rotatable piston rod. See Teleflex, Inc., 299 F.3d at 1327-28 (rejecting limitation of claim scope where neither specification nor prosecution history contained expression of manifest exclusion or restriction evidencing intent to limit meaning of claim term).[2] The Court thus will construe the disputed claims, of which claim 1 is representative, as not requiring a gearbox or a non-rotatable piston rod.

[2] Much of the Court's analysis pertaining to the gearbox limitation applies equally to the non-rotatable piston rod limitation. Like with the gearbox requirement, the Court finds that the non-rotatable piston rod limitation applies only to a preferred embodiment, not the invention as a whole. (See '278 Patent at col. 2, lines 50-67 - col. 3, lines 1-18.) Further, that the embodiment disclosed in the specification describes a non-rotatable piston rod does not mean that all embodiments must have a non-rotatable piston rod. See Liebel-Flarsheim Co., 358 F.3d at 906. The Court finds that, as with the gearbox requirement, the specification does not clearly disavow or disclaim embodiments lacking a non-rotatable piston rod.

IT IS THEREFORE on this 22nd day of July, 2009, **ORDERED** that the Court finds that claims 1 and 7-26 of United State Patent No. 7,241,278 are construed so as not to require a "gearbox" or a "non-rotatable piston rod."

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge